

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

LCS Group, LLC,

Plaintiff,

v.

**Shire LLC, Shire Development LLC, and
Shire PLC,**

Defendants.

Civil Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

For its Complaint, Plaintiff LCS Group, LLC (“LCS”) states as follows.

Jurisdiction and Venue

1. This Court has subject matter jurisdiction over the claims herein, including under 28 U.S.C. § 1332(a)(1).
2. This Court has personal jurisdiction over Defendants because each resides and/or regularly conducts business in New York and has incurred the liability complained of herein in New York, and at least for the first Defendant because it has consented to this Court’s jurisdiction concerning this dispute.
3. Venue is proper under 28 U.S.C. §§ 1391(b).

Parties

4. LCS is a Connecticut company with a principal place of business in Connecticut. LCS is owned and managed by Dr. Louis C. Sanfilippo (“Dr. Sanfilippo”).
5. On information and belief, Defendant Shire LLC is a Kentucky company with a principal place of business in Kentucky, Defendant Shire Development LLC is a Delaware

company with a principal place of business in Massachusetts and/or Pennsylvania, and each is a subsidiary of Defendant Shire Plc of Ireland (collectively, “Shire”).

Factual Background

6. Dr. Sanfilippo is the inventor of U.S. Patent 8,318,813 (“the ‘813 patent”), granted and issued in November 2012 and attached herewith as Exhibit 1. The ‘813 patent relates to methods for the treatment of Binge Eating Disorder (“BED”), as defined in the DSM-IV-TR, with the drug lisdexamfetamine dimesylate (*e.g.*, Vyvanse®).

7. Dr. Sanfilippo assigned the ‘813 patent to LCS, which subsequently assigned it in 2015 to Lucerne Biosciences, LLC, with LCS remaining the exclusive licensee. Dr. Sanfilippo has been the sole Manager and Member of LCS since the company was formed in Connecticut in March 2008. LCS again owns the ‘813 patent.

Pre-Contractual Communications between Shire and Dr. Sanfilippo

8. For several years before November 2012 and as early as 2008, Dr. Sanfilippo and Shire were in communication regarding the inventions of the ‘813 patent, giving Shire several years to conduct due diligence confirming the integrity and validity of the ‘813 patent before it ultimately issued in 2012.

9. For example, in 2010 Dr. Sanfilippo’s counsel specifically informed Shire’s Tatjana May and James Harrington of the published international patent application disclosing the inventions of the ‘813 patent.

10. In November 2012, Dr. Sanfilippo’s communications included telephone calls with Shire’s Peter Cicala, which included a disclosure to Shire that Dr. Sanfilippo’s wife was then ill with cancer.

11. Also in November 2012, Ed Haug of the Haug Firm, patent counsel to Shire, informed Dr. Sanfilippo by email that his law firm was “meeting with Shire in the next few weeks after we are able to analyze your IP [but] it will take some time for us and Shire to complete its review.”

12. Dr. Sanfilippo’s family situation was discussed with Shire again in future communications, as was Shire’s continuing due diligence related to evaluating the ‘813 patent. For example, in May 2013, Dr. Sanfilippo and his attorney Joe Lucci had an in-person meeting in New York with Shire’s Peter Cicala and Susannah Henderson, and Shire’s counsel Ed Haug and Sandra Kuzmich of the Haug Firm. Following the meeting, on May 21, 2013, Shire’s Peter Cicala wrote to attorney Joe Lucci stating, “I just wanted to let you know we haven’t forgotten about Dr. Sanfilippo. We are still working on our patent evaluation. I will be in touch as soon as I have some news for you.”

The October 24, 2013 Confidential Disclosure Agreement Between LCS and Shire

13. Attached herewith as Exhibit 2 is a “Confidential Disclosure Agreement” effective October 24, 2013 between LCS and Shire (“CDA”). The CDA was prepared by Shire and signed on October 29, 2013 by Shire’s Manager and Chief IP Counsel, James J. Harrington.

14. Shire’s Peter Cicala pressed LCS for the CDA, which was entered just before Shire publicly announced positive Phase III trial results for Vyvanse in BED as defined by DSM-IV-TR criteria, as specifically covered by the ‘813 patent.

15. By its express terms, the purpose of the CDA was to “facilitate the Parties’ discussions regarding a potential business opportunity involving U.S. Patent No. 8,318,813.”

16. Paragraph 7 of the CDA provides, in part, that “[i]n addition to the confidentiality obligations set forth in this Agreement, each Party hereby agrees . . . not to discuss publically

[sic] or with any third party that . . . U.S. Patent No. 8,318,813 includes claims that could relate to the use of lisdexamfetamine dimesylate or Vyvanse®.”

17. The purpose and benefit of the foregoing provision was (a) for Shire, that LCS would negotiate exclusively with Shire and not simultaneously with one or more of its competitors, and (b) for LCS, that Shire would not challenge the validity of the ‘813 patent, in particular, via a Petition for Inter-Partes Review (“IPR”) before the United States Patent Office (“PTO”), which inherently is a public proceeding and also typically involves obtaining third-party expert witness testimony related to the patent’s claims.

18. Shire never terminated the CDA or the confidentiality and non-publicity obligations under Paragraph 7, nor gave any indication that the parties were no longer bound by the terms of the CDA in general or its confidentiality and non-publicity obligations under Paragraph 7, in particular.

19. In fact, in about March 2014, Shire agreed to a request by LCS for an addendum to the CDA providing, in part, that “Shire hereby agrees that LCS may disclose Highly Proprietary and Confidential Information that LCS receives from Shire to Tina Passalaris, who has been advised of the confidential nature of such Highly Proprietary and Confidential Information, and who has read and agrees to comply with the CDA.”

20. Tina Passalaris was Dr. Sanfilippo’s wife, and the foregoing request evidences the seriousness with which LCS, for one, honored and followed the confidentiality and non-publicity obligations under the CDA.

Shire’s Bad Faith IPR Petition

21. Despite knowing full well that the ‘813 patent was valid based on its years of communications with LCS and Dr. Sanfilippo, and its ongoing due diligence under the CDA,

Shire filed an IPR Petition (prepared and signed by the Haug Firm and authorized by Shire's counsel David Banchik) seeking to invalidate the '813 patent on May 9, 2014, just a few months after binding LCS and itself to the terms of the CDA.

22. Shire relied exclusively on a false and fraudulent declaration prepared by Shire and the Haug Firm, and signed by Dr. Timothy Brewerton. The petition (including the declaration) is attached herewith as Exhibit 3.

23. Brewerton's declaration was knowingly false and fraudulent because, in summary, it was and is clearly at odds with the relevant medical literature on eating disorders, obesity and stimulant drugs, including being at odds with Brewerton's own published work related to the diagnosis and treatment of eating disorders. The relevant literature as well as Shire's own public statements to investors and the general public regarding Vyvanse® to treat Binge Eating Disorder, as compared to the declaration, evidences Shire's extensive use of misleading statements and egregious misrepresentations of the relevant state of the prior art, and its omission of other material, dispositive information, all in service of the aim of depriving LCS of its valuable patent rights.

24. In addition to knowing that the IPR Petition was frivolous, on information and belief, Shire and its involved executives and counsel knew, at least as early as the signing of the CDA, that LCS did not have the financial resources to litigate the IPR on its merits, particularly to completion. Litigating an IPR generally requires a budget of at least \$500,000.00, particularly in the pharmaceutical arts and particularly as against a corporate behemoth like Shire.

25. Although LCS appeared in the IPR and attempted to mount an opposition on the merits, LCS could not marshal enough financial resources to maintain its opposition, resulting in the PTO entering an adverse judgment—only on procedural grounds—in June 2015. As a result,

Shire and its co-conspirators, including the Haug Firm, were successful in their fraudulent scheme to invalidate the '813 patent via procedural fiat and in violation of the CDA, and deprive LCS of its extremely valuable patent rights.

26. On information and belief, Shire and its involved executives and counsel also knew, at least as early as the signing of the CDA, that LCS was hamstrung by Dr. Sanfilippo's serious family matters, including the fact that his wife was at that time undergoing treatment for cancer, which took her life in January 2015.

27. As evidenced by Shire's bad faith IPR Petition, Shire made the promises under Paragraph 7 of the CDA fraudulently and with malice, intending not to keep its promises but instead, with the intention of muzzling LCS while at the same time (a) delaying the parties' discussions under the CDA, (b) communicating with a third-party expert witness regarding the patent's claims with the intent of utilizing and publicizing such third-party testimony, and (c) preparing to file—publicly—an IPR in an attempt to have the '813 patent declared invalid as a result of LCS not having the resources to defend the IPR proceeding on its merits, as opposed to the merits themselves, which Shire knew did not support a good faith argument that the '813 patent was invalid.

28. The valuable patent rights LCS lost as a result of the wrongful conduct of Shire and its involved executives and counsel include, but are not limited to, the exclusive right to use, sell and/or license products covered by the '813 patent for the remainder of the term of the patent, through 2030, which rights have a value into the billions based on Shire's own sales.

29. Indeed, on January 30, 2015, the U.S. Food & Drug Administration approved Vyvanse® in the treatment of Binge Eating Disorder in adults with moderate to severe symptoms. Shire immediately began marketing the drug for this indication in the United States.

30. Since its introduction several years ago, Shire's Vyvanse® has generated significant sales revenue for Shire (about \$2 billion per year in recent years), mainly in the United States and for the treatment of Attention Deficit Hyperactivity Disorder.

31. In addition, Shire's wrongful conduct usurped LCS's ability to teach and produce literature about treating Binge Eating Disorder based on the very language of the '813 patent, which language is now included in Shire's prescribing and marketing literature related to Vyvanse®, including in the drug's package insert.

32. Needless to say, Defendants' duplicity, fraud and bad faith breach of the CDA caused LCS extreme financial distress and harm, and caused its lone Manager and Member, Dr. Sanfilippo, extensive personal, financial and emotional distress, particularly at a very difficult time while dealing with his wife's cancer diagnosis and treatment, deterioration, and ultimate passing, much too young.

33. Paragraph 10(a) of the CDA provides, in part, that "[t]he Parties irrevocably agree that the United States District Court for the Southern District of New York shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with this Agreement and that, accordingly, any proceedings arising out of or in connection with this Agreement shall be brought in the United States District Court for the Southern District of New York," and further, that each party "expressly consents and submits to the personal jurisdiction of the federal and state courts in the state and county of New York."

First Claim—Breach of Contract

34. LCS hereby repeats and re-alleges the foregoing allegations as if fully set forth herein.

35. In Paragraph 7 of the CDA, Shire “agree[d] . . . not to discuss publically [sic] or with any third party that . . . U.S. Patent No. 8,318,813 includes claims that could relate to the use of lisdexamfetamine dimesylate or Vyvanse®.”

36. LCS honored Paragraph 7 of the CDA by discussing the ‘813 patent exclusively with Shire, and not with any third parties. LCS even went so far as to pursue an addendum to the CDA before having any discussions with Dr. Sanfilippo’s wife, but by the time it was agreed to (after much delay) by Shire, her health had deteriorated and the addendum was never executed.

37. Shire never communicated any termination of the CDA or any termination of the confidentiality and non-publicity obligations under Paragraph 7 of the CDA.

38. In breach of the CDA, in May 2014 Shire filed—publicly—an IPR with the PTO in an attempt to have the ‘813 patent declared invalid. In the IPR petition itself, Shire publicly disclosed that the ‘813 patent “includes claims that could relate to the use of lisdexamfetamine dimesylate or Vyvanse®.” *See, e.g.,* Exhibit 3 at 13 and *passim*.

39. Shire also breached the CDA in retaining Dr. Brewerton as an expert witness for its IPR petition, clearly with the intent of making public his testimony regarding the patent’s claims which specifically relate to the use of lisdexamfetamine dimesylate or Vyvanse®.

40. Shire’s breach of the CDA caused LCS to suffer actual damages including lost profits, in an amount to be determined at trial, plus consequential damages including attorney fees and expenses, and it also resulted and continues to result in unjust enrichment to Shire. LCS’ damages are at least into the hundreds of millions over the period from issuance until expiry of the ‘813 patent beyond 2030.

41. LCS also has suffered and continues to suffer irreparable injury which cannot be remedied adequately unless Shire is enjoined immediately from further breaches.

42. As a result of Shire's wrongful conduct, LCS is entitled to damages in an amount to be determined at trial.

Second Claim—Breach of Contract Based on Implied Duty of Good Faith and Fair Dealing

43. LCS hereby repeats and re-alleges the foregoing allegations as if fully set forth herein.

44. In Paragraph 7 of the CDA, Shire "agree[d] . . . not to discuss publically [sic] or with any third party that . . . U.S. Patent No. 8,318,813 includes claims that could relate to the use of lisdexamfetamine dimesylate or Vyvanse®."

45. Under the CDA, Shire had an implied obligation to refrain from acting in bad faith, arbitrarily, or irrationally.

46. LCS reasonably believed at all times (as would any reasonable business in its position) that one purpose of the CDA was to prohibit Shire from making public, whether through an IPR Petition or in any manner that would jeopardize LCS's patent rights, any information about the '813 patent, particularly that it "includes claims that could relate to the use of lisdexamfetamine dimesylate or Vyvanse®."

47. LCS also reasonably believed at all times (as would any reasonable business in its position) that Shire would not use any information provided to it during its due diligence and/or pursuant to the CDA to harm LCS, including seeking to invalidate its patent.

48. Shire at all times had knowledge that one purpose of the CDA was to prohibit Shire from making public, whether through an IPR Petition or in any manner that would jeopardize LCS's patent rights, any information about the '813 patent.

49. Shire's public disclosures about the '813 patent, based on knowingly fraudulent assertions no less, could not have been made in good faith.

50. Shire's public disclosures about the '813 patent and efforts to destroy LCS's valuable patent rights were done in bad faith, and had the effect of depriving LCS of the fruits of its bargain under the CDA while Shire ignored its obligation of confidentiality and sought to destroy LCS's valuable patent rights.

51. Indeed, the CDA bound LCS to confidentiality, and by abiding by the CDA's terms in good faith, LCS was unable to pursue other lucrative opportunities for its patent rights.

52. By contrast, Shire acted pursuant to a wrongful scheme to destroy LCS's patent rights and in doing so has defeated the purpose and benefits of the CDA for LCS.

53. Shire's conduct was wholly inconsistent with the justified expectations of LCS, and was willful, intentional, and in deliberate disregard of the interests of LCS.

54. As a result of Shire's wrongful conduct, LCS is entitled to damages in an amount to be determined at trial.

Third Claim—Interference With Prospective Economic Advantage

55. LCS hereby repeats and re-alleges the foregoing allegations as if fully set forth herein.

56. Each Defendant was aware of the prospective economic advantage to LCS, including but not limited to the market for LCS' many prospective assignees and/or licensees for the '813 patent, many of which are Shire's competitors.

57. Upon information and belief, through their acts including (a) intentionally drawing out and "stalling" the discussions with Dr. Sanfilippo and LCS, (b) using the CDA to muzzle LCS, (c) delaying the parties' discussions under the CDA, (d) secretly preparing to challenge the validity of the '813 patent and retaining an expert witness regarding the patent's claims relating to the use of use of lisdexamfetamine dimesylate or Vyvanse® for such purpose,

and (e) filing an IPR against the ‘813 patent, each Defendant interfered with LCS’ prospective business with other potential assignees and/or licensees of the ‘813 patent, many of which are Shire’s competitors.

58. Each Defendant intended to wrongfully interfere with LCS’ prospective economic advantage, and the intentional interference has caused LCS to suffer actual damages including lost profits, in an amount to be determined at trial, plus consequential damages. Each Defendant’s intentional interference with prospective economic advantage also has resulted and continues to result in its own unjust enrichment. LCS’ damages are at least into the hundreds of millions over the period from issuance until expiry of the ‘813 patent beyond 2030.

59. Each Defendant committed its acts of intentional interference with prospective economic advantage willfully and maliciously to injure LCS’ business and improve its own, thereby entitling LCS to an award of exemplary damages and attorney fees in an amount to be determined at trial.

Fourth Claim—Fraud

60. LCS hereby repeats and re-alleges the foregoing allegations as if fully set forth herein.

61. Each Defendant made false representations with the intent to deceive LCS and Dr. Sanfilippo, including but not limited to the following: (a) that Shire intended to comply, and not breach, the CDA which by its express terms intended to (i) protect confidentiality, (ii) “facilitate the Parties’ discussions regarding a potential business opportunity,” and (iii) not publicize that the ‘813 patent “includes claims that could relate to the use of lisdexamfetamine dimesylate or Vyvanse®;” and (b) that the relevant “prior art” medical literature on eating disorders, obesity

and stimulant drugs supported the contention that the claimed inventions of the ‘813 patent were obvious to a person of ordinary skill in the art before September 2006.

62. On information and belief, each Defendant made the foregoing promises and misrepresentations fraudulently and with malice, intending to deceive LCS and induce justifiable reliance, including with the intention of muzzling LCS and Dr. Sanfilippo while at the same time delaying the parties’ discussions under the CDA so that Shire could prepare and file—publicly—an IPR in an attempt to have the ‘813 patent declared invalid as a result of LCS not having the resources to defend the IPR on its merits.

63. In addition, Defendants filed the IPR Petition on May 9, 2014, relying exclusively on a false and fraudulent declaration prepared by Defendants and signed by Brewerton.

64. Each Defendant knew and was aware of the falsity of its misrepresentations.

65. LCS had a belief in the truth of Defendants’ representations, in part, because each Defendant represented itself as having integrity and honesty.

66. Each Defendant intended that its fraudulent misrepresentations would cause and induce LCS to honor its own non-publicity and confidentiality obligations and pursue a business opportunity with Shire exclusively and in good faith, so as to provide Defendants with the time necessary to prepare and file the IPR and enjoy further ill-gotten gains.

67. LCS justifiably and detrimentally relied on Defendants’ misrepresentations because it honored its own confidentiality obligations and pursued a business opportunity with Shire exclusively and in good faith, over a long period of time when it could have been pursuing other business opportunities with third parties, including one or more of Shire’s competitors.

68. Defendants’ fraudulent misrepresentations have caused LCS to suffer actual damages including lost profits, in an amount to be determined at trial, plus consequential

damages. Defendants' fraud also has resulted and continues to result in their own unjust enrichment. LCS' damages are at least into the hundreds of millions over the period from issuance until expiry of the '813 patent beyond 2030.

69. Each Defendant committed its acts of fraud willfully and maliciously to injure LCS' business and improve its own, thereby entitling LCS to an award of exemplary damages and attorney fees in an amount to be determined at trial.

Prayer For Relief

Plaintiff LCS prays for judgment as follows:

- A. Declaring that Shire breached the CDA;
- B. Declaring that Shire breached the CDA by violating the covenant of good faith and fair dealing;
- C. Declaring that each Defendant intentionally interfered with LCS' prospective economic advantage;
- D. Declaring that each Defendant committed fraud against LCS;
- E. An accounting for damages, including Plaintiffs' lost profits, lost royalty damages, consequential damages, enhanced damages, treble damages, pre-judgment and post-judgment interest, litigation expenses, costs and attorney fees;
- F. Requiring an accounting for damages adequate to compensate for the breach of contract, intentional interference with prospective economic advantage, and fraud, including LCS' lost profits and amounts attributable to each Defendant's unjust enrichment, consequential damages, treble damages, exemplary damages, attorney fees, pre-judgment and post-judgment interest, and costs; and
- G. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands hereby a jury trial on any issues triable of right by a jury.

Dated: March 26, 2018

Respectfully submitted,

/s/ Stephen M. Lobbin

Stephen M. Lobbin (SDNY admission pending)

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